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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,738	09/29/2003	Tony Romeo	14233.12USU1	7816

23552 7590 02/10/2006

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,738	Applicant(s) ROMEO ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-4 , drawn to a method of increasing or decreasing biofilm formation by increasing or decreasing CsrA levels in a biofilm forming bacterial strain, classified in class 435, subclass 71.2.
- II. Claims 5-10 and 22-24, drawn to a method of increasing CsrB levels in a bacterial strain by increasing the levels of active UvrY, or of modulating biofilm formation by modulating the level of active UvrY in the strain, classified in class 435, subclass 71.2.
- III. Claims 11-15, 34 and 35, drawn to a modulator of CsrA activity comprising an isolated nucleotide sequence containing the sequence element CAGGAUG, classified in class 536, subclass 23.1.
- IV. Claims 18 and 19, drawn to a method of increasing biofilm formation in a bacterial strain comprising inducing increased levels of a repeated nucleotide sequence being CAGGAUG, classified in class 435, subclass 71.2.
- V. Claims 20 and 21, drawn to a method of increasing biofilm formation comprising increasing BarA levels or activity in the bacterial strain, classified in class 435, subclass 71.2.

- VI. Claim 25 and 36, drawn to a modulator of biofilm formation in a biofilm-forming bacterial strain said modulator comprising an amino acid sequence selected from a portion of the amino acid sequence of CsrA shown to selectively bind RNA of biofilm-related genes under stringent conditions in vitro, classified in class 530, subclass 350.
- VII. Claims 26-28, drawn to a method of modulating the expression of a RNA containing at least one of several specified nucleotide sequences, and RNA sequences at least 90% homologous to one of these sequences, comprising providing an RNA binding agent specifically recognizing the sequence, classified in class 435, subclass 71.2.
- VIII. Claim 29, drawn to a CsrA binding agent comprising a RNA containing at least one of several specific nucleotide sequences, classified in class 536, subclass 23.1.
- IX. Claims 30-33, drawn to a method of identifying modulators of biofilm formation, comprising identifying agents which modulate the level of CsrA in a biofilm-forming bacterial strain, classified in class 435, subclass 4.
- X. Claims 37 and 38, drawn to a method of modulating glycogen biosynthesis and catabolism in a bacterial strain comprising modulating the level or activity of CsrA, classified in class 435, subclass 71.2.

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- XI. Claim 39, drawn to a method of modulating glycogen biosynthesis in a biofilm-forming bacterial strain comprising inducing the presence within the bacterial strain of a nucleotide having two or more repeats of the sequence CAGGAUG, classified in class 435, subclass 71.2.
- XII. Claim 44, drawn to a modulator of biofilm formation in a bacterial strain comprising an agent having an AHL binding domain and a DNA binding domain and having at least 50% of the activity of sdiA in stimulating UvrA under physiological conditions, classified in class 530, subclass 350.

Claims 16, 17 and 40-43, which are "use claims" have not been assigned to a restriction grouping, since they are drawn to non-statutory subject matter, and their subject matter cannot be properly determined.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, IV, V, VII, IX, X, and XI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, II, IV, V, VII, IX, X and XI comprise steps which are not required for or present in the methods of the other groups: changing the level of CsrA in a bacterial strain (I); changing the level of active

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UvrY in a bacterial strain (II); creasing levels of a repeated nucleotide sequence being CAGGAUG (IV); increasing BarA levels or activity in a bacterial strain (V); providing an RNA binding agent specifically recognizing specific sequences (VII); identifying agents which modulate the level of CsrA in a bacteria (IX); modulating the activity of CsrA (X); inducing the presence of a nucleotide having tow or more repeats of the sequence CAGGAUG (XI). The end result of the methods are different: a strain with altered or modulated CsrA levels (I); a strain with modulated levels of active UvrY (II); a bacterial strain with increased biofilm and increased levels of a repeated nucleotide sequence which is CAGGAUG (IV); a strain with increased BarA levels or activity (V); a strain with modulated expression of particular RNA molecules (VII); identification of agents which modulate the level of CsrA (IX); a strain with modulated glycogen biosynthesis and catabolism (X); a strain with modulated glycogen biosynthesis which is brought about by inducing presence of two or more repeats of the sequence CAGGAUG (XI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group III and Groups IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in at least two different

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methods as evidenced by the use of this product in the method of Groups IV and XI, i.e. in a method of modulating CsrA activity, and in a method of modulating glycogen biosynthesis.

Except for the specific relationships described above, the invention of Groups I-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups III, VI, VIII, XII are not used in or made by the methods of Groups I, II, IV, V, VII, IX, X, XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

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from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ntv
1/26/06


NANCY VOGEL, PH.D.
PATENT EXAMINER